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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,087	02/19/2004	Stephen T. Foley	P0024937.11US	4761
27581	7590	08/18/2009		
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MINNEAPOLIS, MN 55432-9924			EXAMINER HOLMES, REX R	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/782,087	Applicant(s) FOLEY, STEPHEN T.	
	Examiner REX HOLMES	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-31 and 33-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-31 and 33-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/21/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 5, 7-9, 27-29, 31 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cigaina (U.S. Pat. 5,423,872) in view of Douglas (U.S. Pat. 5,292,344).

3. Regarding claims 1-3, 7-9, 29, 31 and 34-36, Cigaina discloses a gastric pacemaker that senses particular electric activity and then provides "on demand" stimulation (Col. 3, ll. 41-45). Cigaina further discloses that the system stimulates to disrupt normal slow waves and prevent emptying of the stomach (Abstract; Col. 1, line 60 to Col. 2, line 12; Col. 2, line 65 to Col. 3, line 7; Col. 3, ll. 20-51; Col. 4, ll. 8-10).

4. Regarding claim 5, Cigaina discloses that the stimulator is programmable and thus inherently has a programmable controller (Col. 3, ll. 41-45).

5. Regarding claims 1-3, 5, 7-9, 27-29, 31 and 34-35, Cigaina discloses a system that senses and then disrupts normal activity, it is silent as to if the gastric pacemaker includes multiple electrodes. However, Douglas discloses a gastric pacemaker that includes multiple electrodes for sensing and stimulating that are located through the stomach and connected to sensing and stimulation channels (Figs. 1 & 2A). Douglas further teaches how the electrodes are connected to the gastric pacemaker on one end

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and the stomach wall on the other end (Fig. 2A). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the gastrointestinal pacemaker of Cigaina with the multiple electrode gastrointestinal pacemaker of Douglas in order to provide the predictable results of increasing the sensing and stimulation sites to provide increased control.

6. Regarding claim 36, Cigaina in view of Douglas discloses a system that senses and then disrupts normal activity, but it is silent as to if the gastric pacemaker withholds stimulation when abnormal activity is present. However, It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Cigaina in view of Douglas, with a stimulator that only stimulates when normal waves are present since it was known in the art that a system that disrupts normal activity is not needed when normal activity is not present and thus withholding stimulation during unnecessary times provides the predictable results of disrupting normal activity without unnecessarily delivering stimulation to the patient in order to further provide the predictable results of increasing the life of the stimulation device, increasing the life of the battery, and to increase the overall quality of life of the patient.

7. Claims 4, 6, 11-18 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cigaina in view of Douglas as applied to claims 1 and 7 above, and further in view of Gordon (U.S. Pat. 6,895,278).

8. Cigaina in view of Douglas discloses a gastrointestinal stimulation device as described in detail above, and further discloses that the stimulator is triggered on classified events and the stimulation is delivered to the stomach in the areas where the

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intrinsic activity was sensed. But, Cigaina in view of Douglas does not teach a power conservation condition, a telemetry system or a way to save sensed data. However, Gordon teaches a power conservation condition that takes into account the time of day and in the absence of a triggering activity (Col. 2, ll. 62-67 and Col. 3, ll. 1-5). Gordon further discloses that the controller contains an internal storage device and the data can be telemetered using an inductive coupling methodology or radio communication methodology (Col. 15, ll. 1-9; Col. 10, ll. 44-58).

9. Regarding claims 6 and 11-13, Cigaina in view of Douglas discloses the claimed invention except for the powersave features. However, It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the gastrointestinal stimulation device of Cigaina in view of Douglas with the power conservation of Gordon in order to provide the predictable results of increasing the life of the stimulation device, increasing the life of the battery, and to increase the overall quality of life of the patient.

10. Regarding claims 14-18, Cigaina in view of Gordon in view of Douglas discloses the claimed invention except for explicitly stating that the stimulation is offset or direct. However, Douglas discloses that multiple electrodes and sensors positioned around the stomach with a programmable stimulator as set forth in (e.g. Figs. 1 & 2A) to provide direct stimulation to the stomach. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation as taught by Cigaina in view of Gordon in view of Douglas, with variable stimulation methods since

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such a modification would provide the predictable results of stimulating the stomach directly or indirectly to provide increased disruption of the normal waves.

11. Regarding claim 30, Cigaina in view of Douglas discloses the claimed device including memory (Douglas 430, 440, 450), but fails to disclose that the device maintains a history of predecessor events. However, Gordon teaches a device that contains memory for storing the stimulation data so that it can be reviewed later to help provide better stimulation (Col. 10, l. 59 to Col. 11, l. 17; Claims 6, 8, 14 and 32). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the gastrointestinal stimulation device of Cigaina in view of Douglas with the memory storage of Gordon in order to provide the predictable result of a history of stimulation events for review to provide improved stimulation in the future.

Allowable Subject Matter

12. Claims 19-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

13. Applicant's arguments filed 5/11/09 have been fully considered but they are not persuasive. The Applicant argues that Cigaina in view of Douglas fails to sense and then stimulate the stomach wall when the gastric activity is sensed to be normal. The Applicant further argues that neither Cigaina and/or Douglas fail to teach a system that performs an analysis of the sensed activity to classify it as normal or abnormal. Cigaina teaches that it senses intrinsic gastric activity and then stimulates to disrupt the normal

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gastric activity of the stomach. The sensing and electrical components of the Cigaina patent teach sensing then disrupting normal activity. For the system to disrupt normal activity it necessarily has to classify the activity as normal before stimulating to disrupt the normal activity. The Applicant further argues that Cigaina teaches detecting electrical activity but fails to provide any details as to what electrical activity is sensed. It is noted that this argument is moot as the claims fail to describe the sensed electrical activity. The claims only state that the electrical activity that is sensed is intrinsic. Since the electrode of Cigaina is implanted in the stomach the sensed electrical activity is intrinsic.

14. The Applicant further argues that Cigaina in view of Douglas fails to classify the gastric activity as either a slow wave or a peristaltic wave. Cigaina discloses that the system stimulates to disrupt normal slow waves. It is noted that the wording of the claim requires classifying the wave as one or the other. In this case Cigaina teaches that it stimulates to disrupt normal slow waves.

15. The Applicant argues that Gordon fails to teach keeping a history of electrical events. The Examiner respectfully disagrees. Gordon teaches a device that contains memory for storing the stimulation data so that it can be reviewed later to help provide better stimulation (Col. 10, l. 59 to Col. 11, l. 17; Claims 6, 8, 14 and 32). Stimulation events are electrical events.

16. The Applicants arguments regarding claims 4, 6, 11-18 and 36 are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REX HOLMES whose telephone number is (571)272-8827. The examiner can normally be reached on M-F 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. H./
Examiner, Art Unit 3762

/George R Evanisko/
Primary Examiner, Art Unit 3762